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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,929	08/31/2001	Kevin P. Baker	P2548P1C21	2450

7590 05/19/2006

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EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,929	BAKER ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/6/06 has been entered.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. j (120 or 1 19(e)) as follows:
The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application; the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See In re Ahlbrecht, 168 USPQ 293 (CCPA 1971).

Upon review of the specification of the parent (or provisional) application and comparison with the specification of the present application, it is determined that the specification of parent (or provisional) application 09/254,311 (the national stage

application of PCT/US98/25108) is not enabling for the use of the instantly claimed invention. PCT/US99/28301 (published as WO 00/32776) is the first parent that discloses the activity of inhibiting proliferation of stimulated T-lymphocytes. The specification of the 09/254,311 parent (or provisional) application does not teach or suggest an enabled use for the claimed nucleic acids. The specification of '311 teaches PRO361 is possibly a mucin or a chitinase, however any use based on these speculations is not enabled. Since PRO361's activity of inhibiting proliferation of stimulated T-lymphocytes is not disclosed in the parent (or provisional) application and cannot be predicted from the teachings of the parent (or provisional) application, the parent (or provisional) application is not enabling for the instantly claimed invention. Thus, the requirements of the first paragraph of 35 U.S.C. 112 have not been met. Accordingly, claims 22-41 are assigned an elective filing date of 1 December 1999.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-41 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The instant specification does not support a utility for the claimed invention for the asserted use of the claimed invention for the asserted use of enhancing the immune response in an individual based on the results of the MLR assay in Example 34 on page

141 of the specification. In Example 34 on page 141, it is stated that "Any decreases (sic) below control is considered to be a positive result for an inhibitory compound, with decreases of less than or equal to 80% being preferred. However, any value less than control indicates an inhibitory effect for the test protein." (lines 33-35). The specification does not provide any values or data for the proteins tested in the assay. The specification does not provide any statistics for the values measured in the assay. The specification provides no information at all regarding the results of the assay except that a certain protein tested positive and the statement that "any value less than control indicates an inhibitory effect for the test protein". For these reasons, it is maintained that a specific and substantial utility has not been provided for the claimed invention.

Claims 25-41 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicant's arguments regarding these rejections, filed 3/6/06 have been considered, but have not been found to be convincing.

Applicants have argued that the specification provides ample description of the MLR assay, including controls utilized, and description of how to evaluate results obtained from the MLR assay data (page 7). Applicants argue that the specification discloses that the "basic MLR assay protocol followed in conducting the experiment

described in Example 34 of the specification is described in Current Protocols in Immunology, unit 3.12, the entirety of which is incorporated in the present specification by reference". However, the specification simply states that the basic protocol for the assay is described in said reference, without disclosing further information such as the exact protocol followed, or the analysis of the data obtained. The instant specification does not support a utility for the claimed invention for the asserted use of enhancing the immune response in an individual based on the results of the MLR assay in Example 34 (page 141 of the specification). The specification at page 141, lines 33-34, states "Any decreases below control is considered to be a positive result for an inhibitory compound, with decreases of less than or equal to 80% being preferred. However, any value less than control indicates an inhibitory effect for the test protein". The specification does not provide any values or data for the proteins tested in the assay. The specification does not provide any statistics for the values measured in the assay. The specification provides no information at all regarding the results of the assay except that certain proteins tested positive and the statement that "any decreases below control is considered to be a positive result for an inhibitory compound". If the claimed invention is to be used for therapeutic enhancement of the immune response of an individual, the question to ask is how are the results of the MLR assay related to the asserted utility of the claimed invention? The previous Office actions go into great depth regarding the nature of the MLR assay and how those skilled in the art use this assay and what kind of determinations can be made about compounds which are tested in this assay. The MLC (a.k.a. MLR) assay is a measure of alloreactivity of one individual to

another individual. This reactivity is governed by the antigenic disparity between the two individuals which are being compared in the assay. Depending on the individuals being tested, the MLC may indicate stimulation if they are HLA-disparate or the MLC may indicate no stimulation if the individuals are HLA- identical. The ability of the claimed invention to inhibit proliferation in the MLC assay may not be a general inhibition of lymphocyte proliferation, but rather a reaction to one of the MHC antigens on the responder cell. The instant specification fails to provide sufficient detail of the assay which was performed and fails to provide any data whatsoever in order for one of ordinary skill in the art to evaluate the conclusion that lymphocyte proliferation was inhibited by the claimed proteins. The art recognizes several controls as being essential for meaningful results for this assay, including autologous controls, a control to determine maximum response, screening for possible HLA antibodies and growth support capabilities (Basic & Clinical Immunology, page 246). There is no indication that these controls were performed. Furthermore, there is known inherent variability of individual cellular responses from day to day, which would clearly dictate the need for internal controls. The specification indicates that CD4-IgG was used as a control, but it is not clear how this would control for background stimulation or provide for a measure of maximal stimulation. Lastly, the specification fails to provide any data or evidence of the results of the assay, therefore, one of ordinary skill in the art cannot evaluate the conclusion of the specification. The specification states that "any decreases below control is considered to be a positive result", however, this does not indicate that statistical significance must occur for determination of a positive result in the assay. For

these reasons, it is maintained that the results of the MLC (a.k.a. MLR) assay do not support a specific and substantial utility for the claimed invention because one of ordinary skill in the art would not conclude that a molecule which tested positive in the assay of the specification wherein "any decreases below control" are considered positive' would be useful as a molecule for therapeutically inhibiting an immune response in an individual (asserted use). There is insufficient data presented, as well as insufficient controls used, to conclude anything regarding the ability of the claimed invention to be used in a substantial way to therapeutically inhibit the immune response of an individual, and further experimentation would be required to use the invention in this manner. Regarding the Declaration of Dr. Fong cited at page 10 of the arguments, there is no indication that the protein in question caused a decrease of proliferation by 20%. It is simply stated in the specification that **any** decrease below the control is considered a positive result. Therefore, it is not clear whether the protein in question, encoded by the claimed nucleic acids, would have any practical utility when an inhibition of the immune response is desired in vivo. Therefore, the rejections under 35 USC 101 and 112 p.1 are maintained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NANCY VOGEL
PRIMARY EXAMINER

N. Vogel
5/11/06